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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,797	06/25/2001	Preeti Lal	PF-0594 USN	5115
27904	7590	11/26/2003	EXAMINER	
INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.) 3160 PORTER DRIVE PALO ALTO, CA 94304			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,797	LAL ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-44 is/are pending in the application.
- 4a) Of the above claim(s) 21-23,31 and 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-30,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>09242003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XXV in Paper No. number is acknowledged. The traversal is on the ground(s) that DNA and protein share a special technical feature since the examples in the PCT Administrative Rules say so. This is not found persuasive because there is no *per se* rule as to what shares a special technical feature and what does not. The structure of the DNA is extremely different from the structure of the protein and both have widely divergent activities. For these reasons, the DNA and protein lack a special technical feature. As further evidence of this applicant is referred below where a rejection under anticipation is made over Rosenthal et al. Where the sequence exists in the prior art unity of invention is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. The status of this application as a 371 of PCT/US99/21565 is acknowledged, as is the claim for priority to both 60/172,226 and 60/131,321.

Information Disclosure Statement

3. The information disclosure statement filed September 24, 2003 has been considered. Please see the attached initialed PTO-1449.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 24-30 and 32-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses a utility of treating "a disorder associated with expression of CYSKP" and recites many diseases and conditions, see specifically page 29, line 29-page 32, line 28 for the list of diseases and page 41, line 15-page 43 line 20 for the list of conditions. Use of the DNA to detect CYSKP-related DNA is discussed at page 40, lines 25-30. The specification fails to provide a specific and substantial utility for DNA having SEQ ID No. 11, however. In the absence of a well-established utility, applicant must provide evidence of some sort establishing a specific and substantial utility. The list of diseases potentially affected by the level of CYSKP does provide a disclosure of a specific utility, that is, to treat diseases associated with CYSKP. However, mere recitation of disorders that may possibly be affected by the expression of SEQ ID No. 11 provides no connection between the two since no evidence is provided of affecting any disease it is considered that no substantial utility is disclosed. Furthermore, the utility of detecting DNA encoding CYSKP is not

enough because the specific and substantial utility of the DNA detected has not been established.

Another aspect of the specification that might be considered as a utility, although not explicitly stated as such, is the disclosure in Table 2 on page 64 that CYSKP-11 is a thymosin family member. This is not considered to be a well-established utility nor a specific and substantial utility. Thymosin β 4 is not particularly well characterized as evidenced by the references cited that discuss research to learn exactly what its function is. No such research is described for CYSKP-11 and it may well have a totally different function even if it is a member of the thymosin family.

Claims 24-30 and 32-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 24 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification does not describe DNA encoding polypeptides having 90% identity to SEQ ID NO: 11 and having the activity of thymosin β 4. Table 2 at page 64 shows that SEQ ID NO: 11 is presumed to be a thymosin β 4 protein. If thymosin β 4 has a utility then SEQ ID No. 11 has that same utility but there is neither description nor indication that applicant had possession of DNA that is 90% identical and encodes a protein that has the same function as the parent sequence. Similarly, the specification does not describe DNA encoding biologically active fragments of SEQ ID No. 11, nor does it describe DNA encoding immunogenic fragments of SEQ ID No. 11. Written description is seen as lacking for the above reasons.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 24 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rosenthal et al.

Rosenthal et al. teach a 188 base pair fragment of DNA corresponding to bases 540-729 of SEQ ID No. 27. They teach use of the fragment to express the protein, this is considered biological activity, thus anticipating claim 24. Since the fragment is at least 60 base pairs long, claim 33 is also anticipated.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. in view of general knowledge in the art.

Rosenthal et al. teach recombinant expression of their fragment of DNA that reads on a fragment of SEQ ID No. 27. It is well known in the art that in order to recombinantly express DNA one places it under the control of a promoter in a cell and culture the cell so as to produce the encoded protein. Thus, it would have been obvious to one of ordinary skill in the art to express the protein according to well-known procedures with the expectation of producing the protein.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Spytek et al. teach new polynucleotides encoding polypeptides that are new members of the thymosin family, see paragraph number 0006.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (703) 308-4471. The examiner can normally be reached on Monday - Friday, 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Robert A. Wax
Primary Examiner
Art Unit 1653